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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,320	02/13/2001	Bernhard H. van Lengerich	BVL-102A	9819

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/782,320	VAN LENGERICH, BERNHARD H.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105 and 108-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 25-31,34,35,37-40,42,46,50,52-59,61,62,64-67,69,70,73,75,79,81-85,91-97,101,103,105 and 108-110.

DETAILED ACTION

Applicants' arguments, filed in the Request for Continued Examination on July 28, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 112 – Written Description (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31, 59, 108 and 109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "derivatives" and "modified starches" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus*. See MPEP 2163. The MPEP lists factors that can

be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful derivatives or modified starches generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. Specifically, the specification does not appear to disclose species of derivatives, and only discloses from where the modified starches are derived at page 12, lines 1-5, and these are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

Claim Rejections - 35 USC § 112 – Indefiniteness (Previous Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 27-31, 34, 35, 37, 38, 42, 46, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 82, 83, 91-93 and 95-97 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is maintained and further applied to claims 26, 50, 108 and 109.

Applicant's Arguments to "at least about"

The Applicant argues it is clear that use of the term "at least" sets the lower limit to "about 40%" as one ordinarily skilled in the art would glean from the context of the present specification. Applicant's specification gives specific examples and ranges which indicate the precise metes and bounds of the term. In the present case, the original specification supports use of the phrase "at least about 40%", and the claims are not amended to include the addition of the word "about" to recapture a broader range as in Chugai. Clear guidance is given in the present specification to those skilled in the art to employ an effective encapsulating amount of matrix material as recited in the present specification at page 12 second full paragraph, and the working Examples give specific amounts and Table 2 at page 42 give specific ranges for amounts.

Examiner's Response

The Examiner disagrees and submits again by adding the term "at least about" it cannot be determined where the lower limit of the range lies. The term about includes

values below 40%, greater than 40% and 40%. Therefore it cannot be determined whether the claims encompass at least 35% or 39%, making the recitation of “at least about 40%" indefinite.

Applicant’s Arguments in regards to "substantially"

The term "substantially" makes it clear that the terms it is used in conjunction with should not be interpreted as requiring perfection or an ideal, and that variations which do not adversely affect desired release properties of the product may be included. The present specification provides clear guidance to those skilled in the art as to mixing and extrusion conditions for obtaining a substantially homogenous mixture, to obtaining a substantially non-expanded, non-cellular structure, and avoiding substantial dextrinization of starch at, for example, page 22 line 12 to page 27 line 3, and page 29 lines 9-13 where exemplary specific densities are provided, and at pages 22, 29,, 32, 33, and 36 where conditions for avoiding excessive dextrinization are provided.

Examiner’s Response

As previously asserted by the Examiner, the term “substantially” incorporates a degree of variation that has not been defined in any limiting way by Applicant. Since “homogeneous”, “non-expanded” and “non-cellular” are definite phrases, and includes some inherent degree of variation insofar as a perfectly “homogenous” composition and a perfectly “non-expanded” and “non-cellular” structure is merely an ideal, it is unclear what modifying function the term “substantially” serves in this context.

Further, Applicant defines "substantially dextrinized" with the term "excessive", which also renders the term indefinite because it is a relative term and it is not defined as to what degree is encompassed by the term "excessive".

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

Claims 31, 59, 108 and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 31 and 59, the term "derivative" is indefinite because it is unclear how far one can deviate from the parent compound without the "derivative" being so far removed therefrom as to be a completely different compound. See the related rejection in the "Written description" section supra.

In claims 31, 59, 108 and 109, the term "modified starch" is indefinite because it is unclear how far one can deviate from the parent compound without the "modified" being so far removed therefrom as to be a completely different compound. See the related rejection in the "Written description" section supra.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al. (4,938,967) in view of Wittwer et al. (US 4,738,724).

Newton et al. disclose pharmaceutical compositions. The dosages are preferably capsules that contain one or more units. Density of conventional tablets and pellets is usually about 1.0 to 1.5 g/ml (1000 to 1500 g/liter) (col. 1, lines 11-13), encompassing claim 34. Selection of the binder determines the rate of release of the active ingredient (col. 1, lines 19-21). The dosage may be a plurality of pellets having a dimension below about 2 mm, encompassing claims 28 and 55. The pellets have a shape that is spherical (col. 7, lines 48-57). The active ingredient comprises 0.0001 to 45% of the compositions (col. 10, lines 30-35). Various active agents may be used such as tonics (encompassing claim 93), anti-inflammatory, enzymes and anti-viral agents (col. 13 to col. 14, line 48). The pellets may comprise a matrix binder and a coating. These serve to control the release of the active. Binders include polymers such as starch and cellulose (col. 8, lines 53-68). Generally water is added to the compositions to aid in pelletisation (col. 11, lines 37-39), encompassing a water plasticizer. The matrix binder may comprise 50% of the particles (col. 10, lines 22-25). Each pellet may comprise a homogeneous blend of the active, the weighing material and the matrix binder components (col. 10, lines 58-60).

The reference differs from the instant claims insofar as it does not disclose a plasticized matrix is used in the disclosed dosage forms.

Wittwer et al. disclose moldable plasticized starch matrices used to deliver active agents. Starches used include those made from corn, wheat and potatoes (col. 7, lines 36-43). The starches may also be pregelatinized and/or dextrinized and/or modified (col. 8, lines 11-14), encompassing claims 26 and 53. Additional components may be added to the starches such as polyvinyl pyrrolidone, methyl cellulose, shellac and polyvinyl-acetate-phtalate (col. 8, lines 25-57), encompassing claims 50 and 79. Plasticizers are used and include glycerol (col. 8, lines 63-68). Lubricants include fatty acids and talc and comprise 0.001-10% based on the weight of the starch composition (col. 9, lines 3-10), encompassing claims 31 and 59. The starch compositions have a water content of 5-25% (col. 17, lines 23-25). Agents delivered by the matrix include pharmaceuticals, chemicals, dyestuffs, spices, fertilizing combinations, seeds, cosmetics and agricultural products. The products may result in a controlled release delivery system for the enclosed substances (col. 22, lines 9-27). The starch content ranges from 8.2% to 80% of the compositions (see Examples).

The reference differs from the instant claims insofar as it does not disclose the matrices are formulated into pellets or granules, the size of granules made from the compositions, or the amount of active agent in a granule.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used a plasticized starch matrix in the formulations of Newton et al. motivated by the desire to

use a moldable matrix comprising starch suitable for use in pharmaceutical formulations for delivering actives, as disclosed by Wittwer et al and supported by MPEP 2144.07.

In regards to the amounts recited in the instant claims such as the amount of matrix material, this is a result effective variable. The matrix material controls the release of the active and the active results in achieving the desired effect for the desired treatment. That being said, it would take no more than routine skill in the art to adjust the amount of matrix binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65.

In regards to the active, Newton et al. disclose the active may comprise 0.0001 to 45% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 1 to 85%, 5% to 50%, 3% to 50% and 5% to 20% of encapsulant (active agent) consistent with the In re Peterson decision.

It would have been obvious to have coated the actives before incorporating them into the matrix of Wittwer et al. motivated by the desire to add an additional control release mechanism for the active agent as suggested by the teachings of Newton et al.

In regards to the starch being "not substantially dextrinized", Wittwer et al. disclose the starches may or may not be dextrinized, thus encompassing the limitation.

2) Claims 42, 69, 70, 84 and 108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al. (4,938,967) in view of Wittwer et al. (US 4,738,724) as applied to claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 in further view of Jane et al. (US 5,397,834).

Newton et al. and Wittwer et al. differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat.

Jane et al. disclose biodegradable thermoplastic components made of the reaction of a starch aldehyde with protein. Suitable starches include those derived from durum wheat (col. 4, lines 41-50). The reference differs from the instant claims insofar as it does not disclose the thermoplastic compositions are formulated into discrete particles comprising an active agent.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used wheat durum as the starch source in the compositions of the combined teachings of Newton et al. and Wittwer et al. motivated by the desire to use a source comprising starch suitable for making thermoplastic compositions as disclosed by Jane et al. and supported by MPEP 2144.07.

Claims 25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105 and 108-110 are rejected.

Claim 94 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612